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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,157	03/18/2004	John Walter Liebeschuetz	X14659B	6498

25885 7590 09/20/2006

ELI LILLY & COMPANY
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EXAMINER

HABTE, KAHSAY

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 09/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/803,157

Applicant(s)

LIEBESCHUETZ ET AL.

Examiner

Kahsay Habte

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 10/030,187.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/18/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 36-46 are pending in this application.

Election/Restriction

2. Applicant's election without traverse of Group VIII, Claims 36-46 filed 8/21/2006 is acknowledged.

Information Disclosure Statement

3. Applicant's Information Disclosure Statement, filed on 03/18/2004 has been acknowledged. Please refer to Applicant's copies of the 1449 submitted herewith.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. In claim 36, the process of making compounds of formula (I) is not clear in regard to making compounds with $R_r = R_g$. Applicants define R_r as $(CH_2)_c-R_c$, CHR_eR_f , $CH_2CHR_eR_f$, $CH_2CH_2CHR_eR_f$ or R_g where $c = 1-2$. The synthesis step in (b) does not

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cover the situation when $R_r = R_g$. Note that R_g does not require a carbon linker. The synthesis in step (b) at least has one C atom separation between R_c and the piperazine ring. Where is the step that covers the definition of R_g (i.e. no linker between the piperazine ring and the phenyl ring or the dioxobenzo[b]thiophene ring?

b. In claim 36, the proviso and the first definition of R_g is not clear. R_g is defined as 2-methylsulphonylphenyl which may bear 4-fluoro substituent and in formula (K) applicants are excluding a methyl sulphonylphenyl moiety that can be substituted by fluoro at 4-position. Is this the same moiety that is claimed and then excluded by proviso? Or is it a nomenclature problem? Is the methyl attached to the SO_2 group or to the phenyl?

c. In claims 36, 38, 40-41 and 44, the term "amido" is indefinite. There is no way of knowing whether applicants intend just carboxylic acid amides, or whether sulfonic, phosphonic, etc. amides are intended. But even if carboxylic acid amido is intended, the term is undefined. Such a molecule generically has the formula $RC(O)NR'R''$. One of the R choices will be used to attach, depending on whether the amido is C- or N-bound. Which end is intended for attachment? What is the nature of the other two R groups? Can the two of them together form a ring, and if so, of what type?

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d. Claim 39 is rejected because it fails to narrow down the claim limitation of claim 38. Note that this claim was recited originally because of various definitions of Cy before the restriction was made. It is recommended that applicants delete this claim or recite "unsubstituted phenyl" to overcome this rejection.

e. In claims 41 and 44, the terms "Pg₃ represents an amino protecting groups" or "Pg¹ represents an amino protecting group" is indefinite. What is covered and what is not? How can one tell if a compound is an amino protecting group or not? It is recommended that applicants recite specific amino protecting groups as it was done in claims 42-43 and 45-46 to overcome this rejection.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Kahsay Habte', with a stylized, cursive script.

Kahsay Habte
Primary Examiner
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KH
September 15, 2006